MINUTES OF MEETING OF
AMBULATORY SURGICAL SERVICES TECHNICAL ADVISORY COMMITTEE
Department of Community Health, Division of Health Planning
2 Peachtree Street, 34th Floor Conference Room
Atlanta, Georgia 30303-3159
Tuesday, August 26, 2003 ■ 12:30 pm – 3:30 pm

William "Buck" Baker, Jr., M.D., Chair, Presiding

MEMBERS PRESENT

Tary Brown
Sylvia Caley, RN, JD
Clay Campbell
Kevin Chilvers
Kathy Floyd
J. Keener Lynn
Wallace McLeod, MD
Mark M. Mullin
William T. Richardson, FACHE
Marty Rotter for Carol Zafiratos
Raymer Sale, Jr
William Silver, MD
David Tatum
Don E. Tomberlin, Sr.

MEMBERS ABSENT

Billy Carr
Daniel DeLoach, MD
Stephanie Simmons

GUESTS PRESENT

Todd Bacon, Northeast Georgia Health System
Jennifer Bach, Gill/Balsano Consulting
Armando Basarratte, Parker, Hudson, Rainer & Dobbs
Davis Dunbar, Piedmont Hospital
J. Ellesyn, South East Surgical Center
Wytaria Harley, Children's Healthcare of Atlanta
Alex Jackson, St. Joseph's/Candler
Stan Jones, Esq., Nelson Mullins
Bill Lewis, Phoebe Putney Hospital
Bob Moor, Health America Realty
Joe Parker, Georgia Hospital Association
Charul Patel, The Strategy House
Stacy Pineo, Phears & Moldovan
Raja P. Reddy, MD, Reddy Solutions
Kevin Rowley, St. Francis Hospital
Temple Sellers, Esq., Georgia Hospital Association
Richard Sorrells, Reddy Solutions
Monty Veazey, Georgia Alliance of Community Hospitals
L. Fressell Watkins, Powell Goldstein
Deborah Winegard Esq., Medical Association of Georgia

STAFF PRESENT

Richard Greene, Esq
Valerie Hepburn
Jamillah McDaniel
Rhathelia Stroud, Esq.
Stephanie Taylor

WELCOME AND INTRODUCTION OF DIVISION DIRECTOR

The meeting of the Ambulatory Surgical Services TAC began at 12:40 pm. The Chair welcomed members and guests and asked Richard Greene, the new Director, Division of Health Planning, to introduce himself to TAC members.

Mr. Greene indicated that he is an attorney with 12 years experience in private practice and has extensive familiarity with the Certificate of Need (CON) laws of the State of Georgia. He served as a member of the Georgia State Senate and was involved in drafting the 1984 revisions to the CON statutes for the State of Georgia. He was very involved in health care legislation, including authorizing the first outpatient care bill in the United States. Also, he is a former Administrative Law Judge and most recently worked as Assistant to the Chief Financial Officer, Governor Purdue. Mr. Greene said that he looks forward to the challenge of working for the Department.

Dr. Baker provided members with a general overview of the TAC's planning process. He said that, to-date, the TAC has held three meetings and a public forum. He publicly thanked Coliseum Medical Center in Macon, Georgia for hosting the public forum and TAC members for allocating additional time to attend the forum. Nearly 30 persons attended the forum, 10 of whom provided comment. He further noted that the Department has received correspondence regarding the draft rules. All correspondence received prior to August 14, 2003 was mailed to TAC members. All correspondence received subsequent to that time is included in member packets. He reminded members that the proposed rules do not address those single-specialty, physician-owned ambulatory surgery centers exempt by Georgia law and encouraged members to stay focused during the committee's deliberations on those areas about which the committee has purview. He said that, following today's meeting, a draft plan and rules would be sent to TAC members for input at the next meeting.

Dr. Baker provided the TAC with an update of the Health Strategies Council's (Council) meeting that was held on August 22nd. He mentioned that the Commissioner of the Department of Community Health, Tim Burgess, attended the Council's quarterly meeting. At that meeting, Mr. Burgess indicated that he would like to engage the Council in policy discussions regarding Medicaid Reform. Council members were pleased about this opportunity.

REVIEW AND ADOPTION OF MINUTES OF JULY 22ND MEETING

A motion to accept the minutes of July 22nd was made by Dr. McLeod and seconded by Bill Richardson. The motion carried unanimously.

REVIEW OF INFORMATION IN MEMBER PACKETS

Dr. Baker mentioned that the following materials are included in member packets:

- Outline of the key areas that was addressed in correspondence to the TAC regarding the draft Ambulatory Surgical Services Guidelines (correspondence received by the Division of Health Planning as of August 14, 2003);
- Draft Ambulatory Surgical Services Guidelines (dated July 28, 2003);
- Issues identified through correspondence to the Department of Community Health/Division of Health Planning and/or TAC Chair regarding the exempt single-specialty, physician-owned

ambulatory surgery centers. (Dr. Baker reiterated that these issues are outside of the purview of the committee);
- Statement on Scope of Practice and Credentialing from the American Society of General Surgeons; and
- Copies of all correspondence received by the Division of Health Planning regarding the Draft Ambulatory Surgery Services Guidelines (received after August 14, 2003)

Because members did not have a chance to review correspondence received by the Department subsequent to those that were mailed, members were allocated additional time to review all correspondence.

CONSENSUS OF OUTSTANDING ISSUES AND REFINEMENT OF DRAFT GUIDELINES FOR AMBULATORY SURGICAL SERVICES

Richard Greene told members of the committee that he, in consultation with DCH Commissioner Tim Burgess and Dr. Baker, invited Valerie Hepburn to attend today's TAC meeting and to facilitate the finetuning of the draft guidelines. Mr. Greene said that, because he is new to the Department and because he has not previously participated in the committee's deliberations, that Ms. Hepburn's involvement would be the best mechanism to ensure continuity of the planning process. Ms. Hepburn graciously accepted the invitation to work with the TAC.

Ms. Hepburn reminded members that the draft guidelines that are being refined today are those that were previously mailed to members (dated July 28th). She indicated that she would be working directly from the document entitled "Key Areas Addressed in Correspondence to the Ambulatory Surgical Services Technical Advisory Committee Regarding Draft Ambulatory Surgery Services Guidelines (Received as of August 14, 2003)". This document provides an outline of those areas that were addressed in correspondence to the TAC from a wide range of constituents and about which the committee can make some specific recommendations. Most correspondence addressed the following standards: Applicability, Definitions, Need Methodology, Adverse Impact, Financial Accessibility and Quality of Care Standards. Ms. Hepburn solicited additional areas of concern from members of the TAC. None were offered.

Ms. Hepburn said that there were several areas of concern outlined in correspondence to the TAC. Some correspondents sought clarity about the Department's interpretation of several standards contained in the draft guidelines. She identified three (3) areas that required clarification and indicated that following discussion of each area, the item would be voted upon. Following consensus of those three areas, the TAC would then proceed to address other standards which may garner more discussion. The committee agreed to proceed in this fashion. Ms. Hepburn outlined the following three areas and made the following clarifications:

- DEFINITION
  Clarify that replacement means "same number of rooms"
  Ms. Hepburn indicated that it was the intent of the Department to interpret the replacement definition to mean that any replacement of a facility would involve new construction solely for the purpose of substituting another facility for an existing facility with the same number of ambulatory surgery operating rooms. There was concern expressed in correspondence to the Department that applicants could attempt to replace and add more rooms in the replacement process if this additional language was not inserted to clarify the Department's intention. The Department agreed

that misinterpretation could be avoided by adding the following specific language to the draft guidelines: replacement means new construction solely for the purpose of substituting another facility for an existing facility with the same number of operating rooms. TAC members unanimously accepted the inclusion of this clarification language in the guidelines.

- NEED METHODOLOGY
  Clarify that capacity is 1,250 patients and optimal utilization is 1,000 (80% of capacity).
  Ms. Hepburn indicated that it has been the Department's prevailing practice to interpret this methodology to mean that capacity is 1,250 patients per operating room/per year and optimal utilization is 1,000 patients per operating room/per year. Because there was some concern that there is potential for these numbers to be misinterpreted, the Department has agreed to add the following clarification language: determine the number of operating rooms needed by dividing the number of projected ambulatory surgery services patients (step II) by the optimal utilization per operating room. *Capacity per operating room per year is 1,250 patients; optimal utilization is 1,000 patients per operating room per year.*

  Committee members asked about correspondence received by the Department which indicated that optimal utilization should be approximately 1,846 patients. Ms. Hepburn indicated that the correspondent utilized data from the Federal Ambulatory Surgery Association (FASA) and the American Hospital Association (AHA). Both of these data sources incorporate data from hospitals, multi-specialty and single-specialty, physician-owned centers. She noted that there is no comparable data for all Georgia's facilities. Georgia data does not include reporting from single-specialty, physician-owned providers. Additionally, she mentioned that this data examines the number of procedures, whereas Georgia data examines the number of patients.

  TAC members voted unanimously to accept the inclusion of this recommended clarification language in the guidelines.

- QUALITY OF CARE
  Clarify the role of Certified Registered Nurse Anesthetists (CRNA)
  Ms. Hepburn indicated that Certified Registered Nurse Anesthetists are authorized to practice under Georgia state law and have specific scope of practice guidelines to which they adhere. The draft rules cite American Society of Anesthesiology (ASA) guidelines. These guidelines govern physician practice patterns. She further clarified that it is not the Department's intent to impede the practice guidelines of CRNAs and, as such, will work with Department attorneys to craft appropriate language to clarify the intent of this standard. This language will be clarifying in nature and will rely on comments provided by the Georgia Association of Nurse Anesthetists.

  TAC members voted unanimously to accept the inclusion of some clarification language in the guidelines to address practice guidelines of CRNA for standards 3 and 4 (page 9).

Following these recommended administrative changes, members reviewed all other outstanding issues that were identified in correspondence to the TAC regarding freestanding ambulatory surgery centers including the following:

APPLICABILITY

The following recommendation was identified through correspondence to the TAC:

- *Not allow existing ambulatory surgery centers to expand the number of operating rooms without prior CON approval. (Applicability, #6)*

Ms. Hepburn reviewed the Department's current regulatory review practice which allows an existing provider to increase the number of operating rooms in a facility provided that to do so would not trigger the capital expenditure threshold. She said that a CON would only be required if the capital expenditure threshold is triggered. This practice is true for all services that are regulated by the CON process. The committee unanimously agreed that the applicability standard should remain as is.

A member asked if a replacement facility would be required to meet the 3% Indigent/Charity Care Commitment requirement. Ms. Hepburn indicated that a replacement facility would not be required to meet the need methodology or the adverse impact standards but would be required to meet all other provisions of this chapter, including Indigent/Charity Care commitments.

DEFINITIONS:

The following recommendations were identified through correspondence to the TAC:

- *Request classification of General Surgery as a single-specialty service.*
- *Request classification of Interventional Radiology as a single-specialty service.*
- *Delete vascular surgery and/or colon/rectal surgery from the list of single specialty services.*
- *Incorporate language to allow the replacement and relocation of existing ASC beyond a 3-mile radius.*

Ms. Hepburn said that the Department considers General Surgery as a multi-specialty discipline. She said that when the legislation (O.C.G.A. 31-6-2(14)(G)(iii)) was passed to exempt single-specialty, physician-owned surgical facilities from CON, the intent of the legislation was to limit this exemption to specialties with very limited scope of practice. She brought the committee's attention to the Statement on Scope of Practice and Credentialing issued by the American Society of General Surgeons (ASGS) which states:

> "General Surgery is a comprehensive discipline that encompasses knowledge and experience common to all surgical specialties. The General Surgeon Specialist has primary responsibility and expertise in the areas of the abdomen and its entire contents, breast, head and neck, vascular system, endocrine system, oncology, trauma and critical care. The General Surgeon Specialist has the experience and training to manage common problems in plastic, thoracic, pediatric, gynecologic, urologic, neurologic, and orthopedic surgery*".*

Ms. Hepburn indicated that this statement from the ASGS confirms the wide breath and scope of practice of the general surgeon and it supports the Department's contention that general surgery is a multi-specialty discipline. She reiterated that the Letter of Non-Reviewability (LNR) legislation was established to allow CON exemption in some very narrowly defined circumstances. Because general surgeons have broad latitude to perform a wide range of surgical procedures on all parts of the body, the Department contends that it is a multi-specialty and should remain as such.

Ms. Hepburn said that radiology is considered a medical specialty but questioned whether it is a surgical specialty. She expressed concern about allowing surgical procedures to be performed by non-surgical specialists. She asked for clarification and input about the policies of the Centers for Medicare and Medicaid Services (CMS) regarding the scope of practice for this specialty. Members deferred to the list of

procedures that CMS has approved and is attached to correspondence from Reddy Solutions (applicant seeking this single-specialty designation).

The committee engaged in a significant amount of discussion surrounding these issues. Some of the discussion points included the following:

- Concern about the range of services that are being performed outside of the setting of the hospital. Some members indicated that surgical services are among the last remaining profit centers for hospitals. Some members also stated that surgical services support some of the key missions of the hospitals including trauma system network, emergency services, uninsured patient care and other community-based activities and services;
- The State of Georgia is listed among the top 5 states in the nation with the largest number of ambulatory surgical centers. Some members questioned whether the supply was driving the demand for services;
- Members were divided on the issue of which setting (hospital vs. outpatient setting) would provide the patient with the highest quality and most cost-effective care.

Following this discussion, a motion to include general surgery and interventional radiology on the list of single-specialties and to retain colon and rectal surgery and vascular surgery on the list of single-specialties was made by Dr. McLeod, seconded by Dr. Silver. Members voting in support of this motion (4); Members voting in opposition to this motion (10). The motion failed. As such, the list of single specialty services proposed by the TAC includes the following:

dentistry/oral surgery,
dermatology,
gastroenterology,
obstetrics/gynecology,
ophthalmology,
orthopedics,
otolaryngology,
neurology,
pain management/anesthesiology,
physical medicine and rehabilitation,
plastic surgery,
podiatry,
pulmonary medicine, or
urology.

The committee focused its discussion on the recommendation to incorporate language to allow the replacement and relocation of existing ASCs beyond a 3-mile radius. Ms. Hepburn indicated that under the current rules, an ambulatory surgery center cannot move from its current location without the submission of a CON. The language in the proposed rules would allow replacement in some very narrowly defined circumstances. This proposed language would provide the facility with some flexibility to replace itself should market trends dictate such a change. She further reiterated that the suggested distance language (3-mile radius) is currently used in the Department's Short Stay General Hospital rules. Members of the Short Stay General Hospital TAC felt that the 3-miles radius seemed reasonable and justifiable and agreed that an applicant could reasonably contend that they could continue to serve essentially the same patient base within a three-mile radius.

Following committee discussion, Dr. Silver made a motion to change one sentence of the replacement definition to read as follows: "New construction may be considered a replacement only if the replacement site is located within a five (5) mile radius or if the applicant can prove that it is serving essentially the same patient base, based on same payor and patient mix". Motion was seconded by J. Keener Lynn. Members voting in support of this motion (4); Members voting in opposition to this motion (8). The motion failed.

The following language will be retained in the draft rules: "New construction may be considered a replacement only if the replacement site is located within a three (3) mile radius or less from the ambulatory surgery facility being replaced".

NEED METHODOLOGY

The following recommendation was identified through correspondence to the TAC:
Adopt a three (3) year planning horizon.

Ms. Hepburn indicated that historically, the Department has used a 5-year planning horizon for diagnostic equipment and acute care services and a 3-year planning horizon for long-term care services. Dr. Baker inquired as to whether there have been any major concerns or issues raised in the CON review process with specific regard to the planning horizon for ambulatory surgery services. None was indicated. He made a motion to keep the planning horizon at 5 years. Members voted unanimously to maintain the 5-year planning horizon.

ADVERSE IMPACT

The following recommendations were identified through correspondence to the TAC:

- *Recommend that Adverse Impact be considered on all hospitals not just safety net hospitals.*
- *Recommend that sole county hospitals in rural areas be part of the adverse impact criterion.*

Ms. Hepburn indicated that currently an applicant has to meet the need methodology and, in addition, the aggregate utilization rate in the applicant's planning area must equal or exceed 80% during the most recent survey year before additional services can be initiated in the applicant's planning area. In addition to these standards, an applicant would be required to address impact on any safety net hospitals in the planning area. Ms. Hepburn said that the state has an interest in ensuring the stability of safety net hospitals because they, among other things, operate in high-risk environments, provide expensive services, provide valuable teaching opportunities for the state's healthcare workforce, and provide a significant amount of the state's uncompensated healthcare services. She reiterated that not every hospital or sole community hospital is a safety net hospital. The list of safety net hospitals is not static and would be updated annually in conjunction with the Georgia Board for Physician Workforce, the Georgia Department of Human Resources and the Department of Community Health. The criteria for designation as a safety net hospital was crafted by the Short Stay General Hospital TAC and is maintained by the Department.

Ms. Hepburn said that the numerical need methodology determines the need for services in a planning area but some reasonable allowance should be made for those hospitals that the state has defined as safety net hospitals. Some members expressed concern that some hospitals that they would have considered safety net hospitals are not currently on the list of safety net hospitals.

Following committee discussion, no motion was made to incorporate the recommended language into the draft rules. Members agreed to retain the adverse impact statement as indicated in the draft rules (dated July 28).

FINANCIAL ACCESSIBILITY

The following recommendation was identified through correspondence to the TAC:

- *Increase the minimum indigent/charity care commitment for all ASCs to 5% of Adjusted Gross Revenues.*

Ms. Hepburn indicated that all of the state's current CON rules, with the exception of Positron Emission Tomography (PET), incorporate language that requires a 3% indigent/charity care commitment. Members of the PET TAC recommended a 5% commitment because Medicaid does not currently reimburse for these services and this was a mechanism to increase access to these diagnostic services. Several TAC members indicated that hospitals have received significant cuts in reimbursement and that freestanding facilities should be required to absorb some of the cost for the provision of care to indigent patients. Ms. Hepburn indicated that all providers have received cuts in their levels of reimbursement. She reminded members that indigent/charity care commitment shortfalls are placed into the Indigent Care Trust Fund.

A motion to increase the minimum indigent/charity care commitment for all freestanding ASCs to 5% of Adjusted Gross Revenues was made by Don Tomberlin, seconded by Clay Campbell. Members voting in support of this motion (3); Members voting in opposition to this motion (7); Abstentions (4); The motion failed.

Following this discussion a member asked for some clarification about Item F of the Exception to Need standard.

> *F. An atypical barrier to services based on geographic accessibility also may include consideration that an applicant for a single specialty ambulatory surgery service performs specialty procedures that require considerably more time than the need methodology contemplates (e.g., the complexity of the procedure(s) performed by the board certified specialty limits the number of patients that can be served a day on average) and, as such, the applicant contends that need methodology does not correctly reflect the service demand and need for the specialty. In seeking consideration for an atypical barrier, an applicant must document to the Department the lack of availability of that discrete specialty within the planning area, either through a hospital or free standing facility, and must sufficiently document the distinct nature of the services and procedures relative to other procedures measured by the need methodology.*

Ms. Hepburn indicated that the burden of proof is placed on the applicant when an application is submitted under the Exception to Need standard. The applicant would have to justify that the complexity of cases would limit the quantity of cases that could reasonably be performed and could contend that the need methodology is not robust enough to capture this anomaly.

NEXT STEPS

Dr. Baker thanked Valerie Hepburn for her leadership and guidance on the development of these draft rules. He said that the next step would involve the incorporation of all changes that were recommended at today's meeting into the draft rules. In addition to these changes, a draft Ambulatory Surgical Services Component plan and accompanying rules would be mailed to members prior to the final TAC meeting. At

the next meeting final changes will be solicited. Following edits and input from the TAC the plan and rules would be mailed to the Health Strategies Council for action at their November meeting.

Some members asked about the policy recommendations that were identified in correspondence to the TAC. The Chair said that all of the policy recommendations refer specifically to single-specialty, physician-owned ambulatory surgery centers that are exempt from CON regulation. These recommendations are outside of the purview of this committee. He said that under the Goals, Objectives and Recommended Actions section of the Ambulatory Surgery Component plan, it would be noted that several issues were identified that require additional followup. Further, he said that the plan would specifically note that the TAC did not deliberate these issues neither did they reached consensus about these issues.

The final meeting of the Ambulatory Surgical Services TAC is scheduled for Tuesday, October 7, 2003 from 12:30 pm – 3:30 pm. at 2 Peachtree Street, 34th Floor Conference Room.

PUBLIC COMMENTS

Raja P. Reddy, M.D., Reddy Solutions, addressed the TAC about Interventional Radiology.

ADJOURNMENT

There being no further business, the meeting adjourned at 3:15 p.m.

Minutes taken on behalf of chair by Stephanie Taylor.

Respectfully Submitted,

William “Buck” Baker, Jr., M.D., Chair